STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH CARE FINANCING AND POLICY
1100 E. William Street, Suite 101
Carson City, Nevada 89701
www.dhcfp.nv.gov

BRIAN SANDOVAL
Governor

MICHAEL J. WILLDEN
Director

ELIZABETH AIELLO
Acting Administator

Drug Use Review (DUR) Board

Draft Meeting Minutes
October 25, 2012

Nevada State Health Division
3811 W. Charleston Blvd, Suite 112
Vegas, NV 89102

Nevada State Health Division,
4150 Technology Way, Suite 300, Las
Carson City, Nevada 89506

Meeting material may be found at: http://www.medicaid.nv.gov/providers/rx/rxmeetings.aspx

Committee Members Present:

Las Vegas: James Marx, M.D.
Carson City: Chris Shea, Pharm.D. Dave England, Pharm.D.; Larry Nussbaum, M.D

Others Present:
DHCFP:

Las Vegas: None
Carson City: Coleen Lawrence, Chief, Program Services; Mary Griffith, Pharmacy Program Specialist. Darrell Faircloth, Senior Deputy Attorney General

HPES:

Carson City: Ed Arnold

Catamaran:

Las Vegas: Carl Jeffery, Pharm.D. Account Manager;
Carson City: Irene Tobarak

Others:

Las Vegas: Charrissa Anne, J&J; Laura Litzenburger, J&J; John Brokas, Eli Lilly; James Gusted, PPLP; Steve Farmer, Amgen; Bryan Gwyn, Affymax; Gil Astruc, Takeda; Brian McKenna, Takeda; Vinson Lee, Amgen; Scott Larson, BMS
Carson City: Steve Ferreira, ISU College of Pharmacy; Lori Howarth, Bayer

1) Call to Order and Roll Call

Chairman Oesterman called the DUR Board to order at 1:00 PM, October 25, 2012. Roll call, James Marx, MD in Las Vegas, Dave England, Pharmacist, Paul Oesterman,

Pharmacist Chair, Chris Shea, Pharmacist, Darrell Faircloth, Senior Deputy Attorney General, in Carson City. A quorum is present.

2) Public Comment

Chairman Oesterman opened the floor for public comment, none offered.

3) Administrative

An announcement that item number G on agenda under the clinical presentations, the Presentation of Cymbalta use and clinical information will be deferred to the next meeting.

a) **For Possible Action**: Review and approve April 26th, 2012 and July 26th, 2012 Meeting Minutes

Paul Oesterman: we will go ahead and ask the Board members to review and approve both the minutes from April 26 as well as the July 26 meeting. So we need a motion and a second for each of those respectively.

Mary Griffith: Chair, I think we do not have the April minutes it was just the July minutes.

Paul Oesterman: Okay. I stand corrected; it's just the July minutes so we need a motion and a second to approve that.

David England: This is David England I move that we accept the minutes.

Paul Oesterman: I have a motion, do I have a second?

James Marx: Jim Marx, second.

Paul Oesterman: Okay, we have a motion and a second, any discussion on the minutes that are presented before us? Seeing no discussion I will go ahead and call for the vote, all those in favor of approving the minutes as the minutes please indicate so by saying aye.

All: Aye.

Paul Oesterman: All opposed say nay. The minutes passed unanimously by those present.

b) Status Update by DHCFP

i) Public Comment

None

ii) Program Updates

Coleen Lawrence: Good afternoon Mr. Chairman and members? To the big update that we do have, if you haven't already heard, is our administrator Mr. Duarte has resigned from our division after 12 years. We tried with all our due diligence to keep him, we tried to lock him in his office, sticking him to his desk, painting his walls, giving him a new desk and everything else that we could, it did not work, unfortunately. He didn't go far though he is at the University School of Medicine up in Reno. At this point in time we're actually recruiting for a new administrator in the meantime our interim administrator is Betsy Aiello and so when we have a new administrator we'll be announcing at the next board meeting. That's pretty much the biggest announcement that we have.

Paul Oesterman: Okay are there any new program updates or anything? Nothing new, okay.

c) Presentation of 2011 Annual DUR report

Paul Oesterman: Then we have the presentation of the 2011 annual DUR report. This report is one that has already been submitted because of the timing requirements has been submitted to CMS and my understanding there has been no response back from them as of today's date.

Carl Jeffery: Yeah and Mr. Chairman this is Carl Jeffery and that is correct we submitted this; it was due the 29th of September so we had to actually submit it before the meeting. But in the binder, we've included the copy of what was submitted and all of the attachments. So this was kind of challenging because a lot of it was data that wasn't readily available to us so we did the best we could. Certainly there are some gaps in the information but I can say we pulled all the information that we had available.

Paul Oesterman: I have the opportunity to look through the report it looks consistent with what we've submitted in the past and I appreciate the effort you have put into this though. Thank you.

Coleen Lawrence: I should give some clarification to the board members, the reason the date is not available is because of a transition from one system to the other system from MMA to HP. You do have some gaps in the knowledge also because we went from First Databank to Medispan and in doing that we changed our drug data dictionary and so when we change that there is a direct impact with the DUR Board.I think that's program knowledge that we do have to recognize. Our therapeutic duplication edits did change and so how we stored that data was impacted us. So next year we will definitely have a more complete DUR Board report to CMS. Also when you look at this report this is something that all states are challenged with. This is not a very user friendly report; this is not a report that when we all have a look at the report we just kind of go interesting, not very helpful of a report. These are canned fields these are canned reports, there is not a lot of data intelligence honestly to these reports. And I don't mean that to be discrediting to CMS, CMS is evolving this report. In the last two years they've kind of worked on this report and asked from feedback from the state. So I think even next year we will probably see hopefully, different fields in this report. I think the best part of this report is when they ask what the actions of the DUR board has

taken and so what we do is literally go through each one of the minutes and you can see in a narrated form we say everything that the DUR board had taken over each quarter.

Paul Oesterman: Very good. Thank you for the clarification and additional information on that. We're now going to move forward with our clinical presentations and the first one will be the presentation of Prolia use and clinical information. As we go through each of these clinical presentations, we invite public comment and as a reminder each public comment per category is limited to a total of five minutes after which time the public will be asked to terminate their presentation. So do we have anybody in the audience to speak on behalf of Prolia?

Dr. Nussbaum joins the Committee.

4) Clinical Presentations

a) Presentation of Prolia use and clinical information
i) Public Comment

Paul Oesterman: Is there anybody in Las Vegas to speak on Prolia?

Carl Jeffery: Yes.

Paul Oesterman: Okay, so if you could come forward to the microphone, introduce yourself, your capacity.

Vinson Lee: Good afternoon and my name is Vinson Lee, I am a senior regional medical liaison with Amgen, and I'm a pharmacist by training as well. I'm not going to regurgitate the data review that you already have in front of you that you've probably reviewed some of the key points that have already been highlighted within your therapeutic class overview for Prolia. You know we as a company are fine with, as you're aware, we do have the four indications now with the newest indication being for male osteoporosis. Some of the key points that I do want to highlight within your document in the class overview is that many of the guidelines now do point out for denosumab or Prolia to be used as a potential first line treatment. One of the things that it doesn't fall along with our prescribing information however so one of the questions that I had for the panel and the group is your potential prior authorization criteria in that you're looking at a recipient that has experienced inadequate response, adverse event or has a contrary indication to two bisphosphonates.

One of the things that we question is whether the data behind your justification for requiring double bisphosphonate failure, we do have a study that I have provided for you that does show a transition from alendronate to Prolia and has shown after 12 months of therapy after transitioning from the bisphosphonate to Prolia increases the BMD scores that were statistically significant. So, you know, going from inadequate response and adverse event or intolerance to a bisphosphonate and then going to another bisphosphonate, I would question the efficacy there and with us having data to show that you can provide additional efficacy or increases in BMD after utilizing one bisphosphonate and then going to Prolia we request that

the prior authorization be somewhat amended. And the other thing I want to point out is that, if you look at your claims data, it is a very specific patient population that we're looking at, minimal budget impact, it is fairly specific within our prescribing information for indications as you can see from your claims data from Q2 and Q3 it is minimal compared to the overall budget for spent. So I'm happy to take additional questions regarding the data but overall in a, I think the clinical review is extremely thorough. Thank you.

Paul Oesterman: Thank you for your presentation, do any of the board members have any questions for our guest speaker?

Dave England: My name is Dave England I'm a pharmacist, I have a question. do we need to have an exception D section or is it the patient must had to have complications or and two bisphosphonates, Are you saying that we can just get by with just one because I noticed on one of the key points with the medication class it says that sometimes your predicate is used along with alendronate. So are you saying that we should have, the patient should have at least one try, one successful, one treat and one failure with bisphosphonates or not at all?

Vince Lee: No I'm not saying that you can eliminate the bisphosphonates I think most of the, clinical information is going to say that bisphosphonates are going to be front line especially the generics but we would request that that be changed from two to one. And if you look at the prescribing information for Prolia you know basically it's for, if you look at the PMO indication, patient women with osteoporosis have high risk for fracture defined as a history of product fracture or multiple risk factors for fracture all of which is in your prior authorization criteria. Or patients who have failed or are intolerant to other available osteoporosis therapy, it doesn't say therapies so hence not necessary multiple bisphosphonates. And just so you know going from alendronate to an initial, another bisphosphonate it's the same mechanism and action if you think of Prolia as a novel mechanism action as a RANK-ligand inhibitor you're changing your mechanism of action thereby you know increasing potentially BMD scores as I stated earlier with our clinical trial in that area.

Dave England: Thank you.

Chris Shea: This Chris Shea in Carson, when you had stated that there's an increase in the bone mineral density but is there, I didn't read all of your data but is there also a subsequent decrease in fractures, or were the clinical outcomes significant or is it just impact on the bone mineral density?

Vince Lee: In that trial that there was, we didn't look at the fracture risk scoring area was just a BMD scoring. So the clinical end point was BMD not for a risk for fracture for that trial.

Chris Shea: Thanks.

Paul Oesterman: This is Paul I do have one additional question for you, in a number of therapeutic categories there are a number of different products and often times if a patient doesn't respond to one adequately we will switch them to a second one and I think that's part of a rationale for the request in this prior authorization for using two bisphosphonates. Are

you aware of any studies that have demonstrated any therapeutic difference between any of the available products?

Vince Lee: Between the available bisphosphonates I'm not aware of any studies where if you switch from one to another that you actually show either even changes in BMD or even changes in fracture rate. So that's where I'm trying to figure out the data that you would cite for double bisphosphonates failure. So if there's no data to support that how can we basically justify two bisphosphonates and using the same mechanism action if there is no data support? Either changes in BMD I'm not even going to go beyond to changes in fracture rate.

ii) Discussion by Board on Review of Utilization Data

Paul Oesterman: Alright okay thank you, Carl, I'm going to go ahead and let you at this point go ahead and give your presentation.

Carl Jeffery: Okay I want to point out real quick; this is Carl Jeffery for the record. There is handout, they were separate, I want to make sure that everybody has the handout with the updated PA criteria and nothing really changed except just the formatting. So if you have the old one you pulled off the internet before this, it's a little bit different, differently formatted. I will go through the clinical review here as Doctor Lee already pointed out is that the Prolia usage here, and you say it's not a huge impact but anywhere between 40,000 and 20,000 dollars a month that Medicaid is paying for this medication. I don't suspect that this is anything inappropriate, this is a novel agent, the RANK-ligand inhibitor in the class and it's has a little bit different mechanism of action as the other ones where it has the, it actually increases the survival of osteoclasts.

One of the things that really stuck out to me is that there really were no, they were all placebo-controlled trials and there's no comparison to other agents so I think as Dr. Lee actually mentioned too. And some of the other key points that I want to point out from the reviews is that pretty much all these drugs as Dr. Lee also stated was that a lot of the guidelines don't specifically say that one is preferred over the other for first line agent and they kind of lump them all into the same categories but just because of availability and ease of use the bisphosphonates are definitely first line and cost definitely falls into that as well especially where the generics are much cheaper. So the Prolia can be recommended as potential first line therapy and it can be used again alongside with the other bisphosphonates. So the clinical information I was going to discuss real quick and we can move on I want to talk about the prior authorization criteria that's in the new stapled packet that we've got here and it's called the Prolia. As Doctor Lee mentioned it might be a good idea to and it's up for discussion if the board wants to require just one failure or two and you know any other adoptions that changes this.

Jim Marx: This is Jim Marx I don't see any reason to have a fail or two, there's really no difference between the, there hasn't been any demonstrated difference between either the other bisphosphonates why would we have to fail two when we have a comparable efficacy so I don't think there is any justification for requiring two failures.

Paul Oesterman: Thank you, at this point do we have any other information that you wish to present Carl?

Carl Jeffery: No, that's all the information.

Chris Shea: Carl this is Chris up North, I have one question, what are we considering an inadequate response or a failure, is it a lack of not meeting the T score or fracture after being on a therapy bisphosphonate for a period of time, or how do we define that? I guess I'm just trying to sort out in my mind when we would say the bisphosphonate is not working.

Carl Jeffery: Right if you, you know technically you define inadequate response as another fracture but we certainly don't want to lead our population into getting another fracture before they move on to the next agent so you know I think we can continue T scores to see if there's a continued decline after they start the bisphosphonate and I think the biggest in thing in this criteria would be an adverse event or adverse effects like are unable to tolerate and during our pre-meeting with Dr. Oesterman I mean we also discussed adding some criteria about unable to sit up in bed or be able to take this according to the guideline for bisphosphonates.

Paul Oesterman: Okay, do we have any further discussion by the board on this proposed prior authorization criteria? If not we can ask our motion to approve the criteria as they have been submitted, or we can request an approval of this proposed prior authorization criteria amended to just indicate one bisphosphonate in part three of each of the four different diagnosis.

iii) **For Possible Action**: Adoption of Clinical Prior Authorization Criteria.

Jim Marx: This is Jim Marx I would propose an amendment to first strike the requirement that two bisphosphonates be, have failed and also to add an additional criteria that there would be a qualifying criteria as if there was some sort of GI indication whether there is a history of esophagitis or inability to be upright, would also be an indication for first line use.

Dave England: I'll second that.

Paul Oesterman: Okay so the motion that we have on the floor is to approve this proposed prior authorization criteria with amending section three on each of those four diagnoses to read the "recipient has experienced an inadequate response, adverse event or has a contra indication to a bisphosphonate". Now Dr. Marx also wanted to add a fourth criteria and that would be that the "patient has a history of esophagitis or an inability to tolerate a bisphosphonate".

Dave England: I will second that additional amendment as is.

Paul Oesterman: Okay so we do have a motion and a second for the approval of the amended and proposed prior authorization criteria for Prolia or tanezumab, any further discussion?

Daryl Faircloth: Excuse me, for the record, deputy attorney Daryl Faircloth, just for clarity, Dr. Marx, did you mean to add that criteria regarding the inability to sit up to all four of the diagnosis as a fourth criteria that must be met?

Jim Marx: No it would be, it would be a single qualifying criteria, so it would not be a 'and' it would be a 'or.'

Daryl Faircloth: So again that would be the fifth diagnosis that was for a qualifying event?

Jim Marx: I guess that's true, yes, that way it could, it would actually make it another diagnosis, then...

Paul Oesterman: No I don't think, I think there is confusion here. This is Paul; this is something that would fall under each of the indications for the product, postmenopausal osteoporosis, male diagnosis of osteoporosis non metastatic prostate cancer and breast cancer.

Jim Marx: Paul I agree.

Paul Oesterman: And in any of those patient cases…

Jim Marx: Paul I, this is Jim Marx, Paul I agree with you that it should be under each of those.

Carl Jeffery: So and this is Carl, just for clarification maybe those would be a little bit easier that if we just amend that requirement onto section three and each of these criteria, will that be sufficient, so they would read…

Daryl Faircloth: The three little Is?

Carl Jeffery: Would read.

Daryl Faircloth: The three little Is?

Carl Jeffery: Right, so the recipient is experiencing inadequate response, adverse event or has contraindication to two bisphosphonates or has esophagitis or has the inability to remain upright.

Jim Marx: I would agree with that, this is Jim Marx.

Dave England: This is Dave England again, you know I'll accept that amendment for the second that I gave.

Paul Oesterman: Just to clarify though; it is one bisphosphonate not two.

Jim Marx: Right.

Carl Jeffery: Correct.

Paul Oesterman: Any further discussion? Seeing none, we will go ahead and call for a vote; all of those in favor of approving this amended proposed prior authorization criteria for Prolia, please indicate so by saying Aye...

Speakers: Aye.

Paul Oesterman: Alright, all opposed say nay. The amended criteria passes, thank you.

b) Presentation of Forteo use and clinical information
i) Public Comment

Paul Oesterman: Our second clinical presentation has to do with the product Forteo, use and clinical information, again we'll ask, is there anybody in the audience for public comment?

Carl Jeffery: Yes.

Jim Marx: Yes we have..

Paul Oesterman: Okay, if you could introduce yourself and remember there is a five minute timeline.

John Brokers: This is John Brokers I'm with Eli Lilly Company, I'm going to speak a little bit about Forteo and very similar to the last conversation, this is about one tenth of the monthly usage of Prolia, so a very small number of claims per month. A very similar criteria has been established that for the high risk patient, the patient who has a T-score of two point five or higher. Most of the references if you look through the write-up on this one, dating at the earliest 2010 before the update the, bisphosphonates on the super fracture risk patients were, you already have a very fragile bone to add calcium.and the bisphosphonates bones become quite brittle and then you have the super fractures. So to require both a T-score of two point five or greater and then a history of inadequate response to bisphosphonates doesn't quite agree with that and certainly the inadequate response to two bisphosphonates, by this point you've already had a very high risk patient prior fracture, T-scores that are above two point five, it's a very similar discussion. So I'm going to ask for the similar amendments for this product that were proposed in the last product.

Paul Oesterman: Alright, thank you, do the board members have any questions for John regarding Forteo?

Jim Marx: John where do you, this is Jim Marx, where do you see the difference in the indications for the two products, Prolia versus Forteo?

John Brokas: I would follow the evidence that would say it's a high risk, very high risk patient, someone whose had a prior fracture and if you can define it through a T-score, or a Z-score then that's fantastic, it's a difficult thing to implement sometimes and it's a different

mechanism of action I would think that Prolia. So I wouldn't pit this against each other, I would just say the criteria are equally problematic.

Jim Marx: Is there anything you think that would help from a prescriber base that would be helpful to a prescriber to determine which would be a more appropriate choice?

John Brokas: I don't have that…And so I was asked a similar question in Texas and I you know, it's a challenging thing.

Jim Marx: Okay.

Paul Oesterman: Do any of the other board members have any additional questions?

Dave England: In regards to that, the questions you have, and I was thinking the same thing myself just appears that the only difference so I can see from the information that we have is, you know the, there's a hard name here.

John Brokas: Forteo.

Dave England: Yeah the Forteo is as a daily dosing whereas the previous one was just a once a month dosing so if you just narrowed patient convenience…And well that's what it appears to be.

Carl Jeffery: Dave, Prolia is actually every six months.

Dave England: Oh every six months, okay, thank you.

Paul Oesterman: Okay, Carl would you like to go ahead and present…

Carl Jeffery: Sure.

Paul Oesterman: What you have for us.

ii) Discussion by Board on Review of Utilization Data

Carl Jeffery: Yeah so kind of similar to the Prolia before this, you know an agent used for osteoporosis and as John said it was a very high risk patient. Looking at the claims data here in Nevada and not a whole lot of use on here between two to five claims per month, so it's not used quite a bit, but I think one of the reasons I want to put this on the, as for a discussion is for my days of working on the nursing homes. I do remember seeing quite a few people that were placed on this, it wasn't necessary and it's a good product but again it's very costly too. So I think that we just need to make sure that we are on, following up the clinical guidelines appropriately and making sure that we're using the treatments we have available wisely. Forteo is a para-thyroid hormone, its available for the treatment of osteoporosis and it's got, it is as we stated it is given subcutaneous once a day, patients can be taught to give this on their own shot and so I just, I think it's a pen that's pretty easily to train patients how to give. This is one of the few agents that's actually been shown to increase bone mass

whereas the most of the other agents actually do just stop the bone loss so that, it has some advantages in there.

The studies do show it's been compared to some of the other agents and you know I think it's got some good outcomes and one thing that we've referenced it in our PA criteria that it should not be more used more than two years. I don't know how real of a risk it is but when they did the study in the rats and the mice they were getting osteosarcomas. But I think the dose was at several times the human dose. It's got a black box warning the osteosarcomas risk and I think that's limited to long-term use and high dose, so it has been shown to prevent vertebral fractures. The evidence isn't as strong as reducing the nonvertebral fractures and the treatment is not demonstrated for reduction of hip fractures. So the current guidelines recommend that Forteo be used as a potential option for the prevention and treatment of osteoporosis but generally recommended it be reserved for patients that are at a very high risk for fracture or patients who have failed first line bisphosphonate therapy. And I think that's all the clinical information unless you have other questions.

Paul Oesterman: And Carl this is Paul I do have one question you mentioned the differential between vertebral and hip fractures that's my understanding that a lot the vertebral fractures can happen somewhat spontaneously and the biggest concern for quality of life for a patient is in the hip fractures. Do we have any kind of data comparing and contrasting those two?

Carl Jeffery: I mean just the mortality and mobility of the different types of fractures?

Paul Oesterman: Yes

Carl Jeffery: I don't think I don't have any information specifically addressing that in my documentation here and I don't have anything off on top of my head.

Jim Marx: This is Jim Marx, it appears to me the difference between the Prolia and Forteo are really the Prolia may have a first line indication versus the Forteo that really seems to be the difference in our criteria for coverage I don't think it is… So there is a little bit of a difference in indication and coverage?

Paul Oesterman: One additional question that I have here, we have in the proposed prior authorization criteria the fact that the patient is experiencing inadequate response to prior bisphosphonates. If we are now including as we have with the Prolia product, do we want to include that in the limitation or coverage requirements?

Jim Marx: Could you explain what you mean?

Paul Oesterman: Yeah right now he's in post prior authorization criteria we say that the patient has to have experienced something with a bisphosphonate. What is to stop a patient or a physician from ordering the Prolia and the Forteo for a patient concurrently if we don't have anything in the criteria? It just might help to close the loop so to speak

Carl Jeffery: So is it your proposal that we amend this to also require that they try and be either intolerant or some other contraindication to Prolia in addition to the bisphosphonate?

Jim Marx: Or just not concurrently

Dave England: After explaining yourself it made more sense to me too. We need some criteria here since we are treating the same thing or using two different mechanisms, they both have a different mechanism of action, they both have different administration schedules. I see someone thinking well look we can attack this in two fronts rather than one front. So would there be a rationale? Were there any studies that show both of these medications on board at one time during some of the treatment for some of these patients?WBecause again our criteria doesn't say you can't be on both at the same time. We kind of look at this as you've got either or, as opposed to could they both be taken concurrently and I don't see anything in our literature that we have that says we can or can't do that. So I can see someone attempting it.

Coleen Lawrence: Right you have other policies that do not allow for common therapy so you want to put some kind of criteria in there?

Paul Oesterman: Okay I think it will be wise, since the product we're discussing right now Forteo is specifically designed for the high risk patients to go ahead and include in the criteria that the patient has experienced inadequate response or adverse event or has a contraindication to one or two bisphosphonates as we amend that and then also to the Prolia product.

Coleen Lawrence: And may I just suggest to the board that if you don't want to name a specific product that you just say concomitant therapy just because you know if a product comes out tomorrow you don't have to come back and address this drug again.

Paul Oesterman: Thank you.

Coleen Lawrence: And that's just a suggestion if that meets what you are trying to address?

Paul Oesterman: I believe that it does.

Dave England: I guess that there'd may be the question that we might want to ask both of our representatives that are there today. Have there been any head to head studies as comparing one product to another that would give a better outcome or patient criteria that would be better addressed by their particular product rather than I'll say both can be used concurrently because again it's like we're kind of comparing apples and oranges. They have completely different mechanisms of action, completely different administration criteria. So if we were looking at an algorithm to decide how to prescribe this, what would be the first line as opposed to second line as opposed to ongoing down the path we expect the treatment dealing with Prolia before we go to Forteo or vice versa?

Carl Jeffery: Well Dave this is Carl. I'm not aware of any studies that are head to head with Prolia and other agents and all of those trials are placebo controlled but there are several studies with Forteo against other agents. There are several with alendronate and there is also

some with zoledronic acid and I think that its shown to be , you have to forgive me I'm not intimately familiar with this …

Dave England: I mean not to put our representatives on the hot seat down there to kind of put them on the hot seat. Where would, you know, if we were in a physician's office right now and I was a physician saying well you know I've also had the sales representative for Forteo and I also had the sales representative here for Prolia, you tell me what patient population should I initiate therapy with if I already have treatment failure or adverse event with a bisphosphonate? I mean where do we start? Its kind like they are two things, we could start the same horse in the race right now but which horse do I want to start?

Vinson Lee: I mean I think from the perspective of both products and thinking from as a…

Paul Oesterman: Can you excuse me before you continue could you introduce yourself.

Vinson Lee: Sorry Vinson Lee medical liaison with Amgen so I represent Prolia. From the Prolia perspective I mean I think you know the criteria that you've given agrees with the prescribing information as well as the clinical guidelines. I think when it comes down to us versus Forteo what you're looking at really is a clinical judgment from the physicians. I'm not going to say because there are no head to head trials, there is no data to support one over the other. But what I would look at is patient administration, so you are looking at a daily injection versus once every six months and then you are looking at the cost issues. So if you give me a daily injection you are probably going to have a higher cost versus once every six months. It is going to be a lower overall impact on your budget. So those are the two things then it goes back to physician choice you know we are not going to be here to say one should be used over the other because the guidelines are not going to support that. They are probably both going to be used in high risk patients or treatment failure or intolerance to a bisphosphonate. So I think it's going to go back to one administration, two cost and three physician choice.

Dave England: Okay.

Chris Shea: This is Chris up North, I agree with Paul and I guess my concern would be that they're going to end up… could potentially end up on both parenteral drugs and I think it should be left to physician's choice as to which one they would want initiate since we don't have good data as far as a head to head. I don't think we could really sort that out here but my concern would be that we're not paying for both drugs at the same time and if there is a way to write that in and leave the, you know who knows I mean monthly or daily or with every 6 months is up to the physician and patient on that. At least that's my thought.

Vinson Lee: Sorry can I make one more point I'm sorry. I would find it highly unlikely that a physician would put a patient on both of them at the same time. I mean if you are basically going through a treatment algorithm you would probably go from a bisphosphonate to an alternate therapy

Chris Shea: I'm not concerned that a physician would do, it's just you know many times these folks see multiple physicians so yeah I doubt a single primary physician would do that knowingly.

Paul Oesterman: I think if we take Coleen's advice and we just possibly amend the prior authorization criteria on section C of part two to read that the patient has experienced inadequate response and an adverse event or has contraindications to a bisphosphonate or is on concurrent therapy that should cover what we are concerned about.

Coleen Lawrence: Okay.

Paul Oesterman: Any further discussion before we ask for a motion.

John Brokas: I'd feel sheepish if I didn't mention that the main reason I brought this up was patient safety. The double bisphosphonate failure can lead to, in a high risk patient a super fracture which is why the amendment was first produced. I just wanted to make sure that massege was retained.

iii) **For Possible Action**: Adoption of Clinical Prior Authorization Criteria.

Paul Oesterman: Thank you, okay we are now looking for a motion from a member of the board for approval of the proposed prior authorization criteria for Forteo...

James Marx: I make the motion this is Jim Marx.

Dave England: Dave England I will second the motion.

Paul Oesterman: Okay, is there any discussion of the motion. Just to clarify, to make sure that the way the motion reads is as it has been presented. Section two, part C, we've amended that to one bisphosphonate and also included the line pertaining to concomitant therapy.

James Marx: That's correct we, I think that was assumed.

Paul Oesterman: I just wanted to keep it in the minutes here. So any further discussions on the proposed amended prior authorization criteria? Seeing that we will go ahead and call the question, all in favor please indicate that by saying Aye.

Board: Aye.

Paul Oesterman: All opposed say nay.

Paul Oesterman: Great the amended proposed prior auth criteria for Forteo has passed. We are going to take a short five minute recess and we will resume at ten minutes to two.

James Marx: I would move that we amend the previous Prolia motion to restrict the use to times where there is no other second line therapy or third line therapy being used concurrently.

Paul Oesterman: Thank you okay Dave England who seconded that, would you go along with that?

Dave England: Yes I will concur, that second still.

Paul Oesterman: Okay so with this revision we need to have the board vote. All in favor of the revision for the previously approved prior authorization criteria for Prolia please indicate so by saying "Aye"

Board: Aye.

Paul Oesterman: All opposed?

Paul Oesterman: Okay the amendment does carry.

Coleen Lawerence: Do you want public comment on this?

Paul Oesterman: Just for clarification I just want to see if there is any public comment on the revision that we just carried out?

Carl Jeffery: No they just…No, I think they were okay.

Paul Oesterman: Okay good, alright thank you. Our next item on the agenda is…

Gabe Lither: Hey hold up hold up hold up. Hey Paul?

Paul Oesterman: Okay

Gabe Lither: Just for the record we discussed that prior, the public who is interested probably took off though we did advise them that that change will be made before we came back on the record .

Paul Oesterman: Gabe can you just for the record introduce yourself?

Gabe Lither: This was Gabe Lither senior deputy attorney general thanks

Paul Oesterman: Great thank you

c) Presentation of Marinol use and clinical information
i) Public Comment

Paul Oesterman: Alright moving forward with the agenda section 4C the presentation of Marinol use and clinical information, is there any public comment? Or I should rephrase that, any public comment in the room? Okay, seeing none Carl would you like to go ahead and give your presentation?

ii) Discussion by Board on Review of Utilization Data

Carl Jeffery: Okay, so the reason this got put on the agenda was because of our lock in program. We look at medications and the potential for abuse and the recipients receiving those medications have been identified. They are on it routinely which doesn't really meet the criteria for its indications because it is really just indicated for a couple of things, chemotherapy induced nausea and vomiting. So I think we have the room here to maybe make sure that these agents are being used appropriately. Even the generic isn't necessarily cheap and so the state is still spending upward to $50,000 a month for these drugs, when you add up the three different strengths that are available. So you see the usage is not a huge number of claims, covering about 30 claims a month on average and like I said we are spending a good portion on it too. As I kind of eluded to there is only just two indications that Marinol is approved for and that's the chemotherapy induced nausea and vomiting and the AIDs related cachexia.

There is another similar agent and it is called the cesamet or nabilone and it is only indicated for chemotherapy induced nausea and vomiting. Marinol is THC, THCis the active ingredient in marijuana. The studies show that it's has been more effective for complete control of nausea for the first 24 hours of chemotherapy compared to some of the other anti-neuraleptics, or some of the old anti-psychotics. They used Haldol, metoclopramide and prochlorperazine. But the interesting thing was these drugs were not shown to be more effective than placebo.

Cannaboids were not more effective compared to the other agents in very, very high or very, very low immunogenic chemotherapy regimens. So really the place for this therapy is an adjunctive therapy for break through nausea when you have got either high emetogenic therapy and they are already on agents like Zofran or Emend and they want this for the break through nausea. We've got on the first page the criteria that we present here. That is my clinical presentation I'm opened for questions.

Coleen Lawrence: Mr. Chairman this is Coleen, let me give you a few little words on this one also. This drug comes up every legislative session, never fails. And I think from a policy perspective, obviously we cannot tell it is off label unless it is being prior authorized and so this is more also of a preventative gap for us. So we are going to the legislative session and Medicaid is going to be a hot topic this year as we all know because of healthcare reform and everything else in our budget. So I think from just a policy perspective its good measure and as you can see from a quantity dispensed we're kind of all over the board and we can't see what is going on unless we' prior authorize things. And just from a policy perspective for us it is a very good preventative measure to see what is going on behind the scenes. There is definitely a trend with our lock-in program and this capsule, and that is how it has come to our attention.

Paul Oesterman: Very good thank you for sharing that I think that was one of the questions that I have with the number of patients we have in the Lock-in program right now.
Do we have a number of how many there are?

Mary Griffith: 300.

Paul Oesterman: 300 patients okay, so this is very high percentage of concern, are we able to determine the practitioner that is prescribing this product? Is it coming from a relatively small select number of practitioners or is it you know, pretty much across the board hit and miss?

Carl Jeffery: Chairman this is Carl, I know you have mentioned that in the pre-meeting I never got the chance to an opportunity to run those numbers.

Paul Oesterman: Okay, that's fine it would be interesting to know just for the future. Does anybody on the board have any thoughts on the proposed prior authorization criteria that has been presented to us?

James Marx: This is Jim Marx I think it is probably a good idea because certainly we see some indications from our chronic pain patients that they all would like to this adjunctive medication. In my experience it may provide some quality of life improvement but we don't see any of them reducing their medication requirements with it. So I think that limiting through a prior authorization process is a good idea.

Paul Oesterman: I'm going to play devil's advocate for a moment because I do completely agree with you. But if we were to put this under a prior authorization criteria, is there a risk that some of the users of this product might go to outside sources for these products, consume some impure product and end up being hospitalized?

James Marx: Well I think they are probably doing it anyway so I don't think, I think it's sort of a moot point.

iii) **For Possible Action**: Adoption of Clinical Prior Authorization Criteria.

Paul Oesterman: Thank you, you answered exactly as I was hoping. Any other discussion, if not we can ask for a motion and a second to approve the proposed criteria that are presented in front of us.

James Marx: I move for adoption as I had presented, Jim Marx.

Chris Shea: Chris Shea, I'll second that.

Paul Oesterman: Okay, so we have a motion and a second, any further discussion on the proposed prior authorization criteria for both the nabilone and dronabinol products? Okay seeing none, we will call the question, all in favor of these proposed prior authorization criteria please indicate so by saying "Aye"

Board Members: Aye.

Paul Oesterman: All opposed say nay,

Paul Oesterman: Okay the proposed passes as written.

Paul Oesterman: Okay, the proposed passes as written.

d) Presentation of Omontys use and clinical information
i) Public Comment

Our next agenda item is the presentation of Omontys use and clinical information. We'll start off again by asking for public comment, as a reminder public comment is limited to five minutes and please introduce yourself to us.

Brian Gwyn: My name is Brian Gwyn, I'm a pharmacist by training and with Affymax US medical affairs representing Affymax and Takeda Pharmaceuticals.Thank you for the opportunity to comment and present on Omontys during this ESA review. Omontys is a new ESA, recently approved in March by the FDA for treatment of anemia and it helps patients on dialysis. We are asking the state of Nevada committee to continue the current coverage of Omontys and not add a prior authorization. We believe this is supported by several arguments. First of all there is a limited indication for this product; it's only indicated for treatment of anemia in adult patients on dialysis. Patients must first be diagnosed with end stage renal disease to be a candidate for this product. Omontys distribution is strictly limited to dialysis organizations, only dialysis centers may order and receive this product and finally Omontys coding limitations restrict coverage and reimbursement to ESRDs only.

Just want to briefly review the key clinical data for Omontys as well, for over two decades in the US, only one ESA, Epogen has been available and so now as of March, dialysis patients and their providers do have a choice for ESA therapy. The approved indication for Omontys is for the treatment of anemia in adult patients again and only on dialysis. This was the only indication sought from the FDA and therefore the only indication approved. It is not approved for oncology patients, pediatric patients or CKD patients not on dialysis. Again Omontys is for dialysis patients only and is dosed once monthly compared to Epogen which is given one to three times per week.

Regarding the safety and efficacy, the safety and efficacy was demonstrated in two large randomized head to head trials against Epogen. Due to some class wide safety concerns from other ESA trials reported in the mid-2000s, CHOIR, CREAT, TREAT, etcetera, the FDA required that the phase three studies for Omontys look specifically at cardiovascular safety. This is the first time for any ESA, so these two Omontys trials and dialysis represent the largest and longest trial ever in the ESAs and set a new high bar for safety. If we look at that primary safety evaluation included a composite cardiovascular safety end point with six end points, all cause death, MI, stroke, CHF, unstable angina and arrhythmia. he safety end point was easily met with a hazard ratio of 0.95 which is obviously below one.

The primary efficacy endpoint and maintaining hemoglobin was also easily met and therefore similar in efficacy to Epogen. This data demonstrated for the first time that you can see similar control of hemoglobin in these patients with once monthly dose of Omontys compared to the other agent that's used one or three times per week. Once monthly administration offers advantages for dialysis patients and nursing staff. So to summarize, Omontys is the first ESA for use in dialysis in over 20 years. It's the only once monthly agent for dialysis in the United States and finally strict distribution controls encoding limitation already restrict Omontys for the patients for whom the drug is intended.

Carl Jeffery: This is Carl, one quick question for you, you've mentioned coding restrictions, what restrictions in coding are you referring to?

Brian Gwyn: So I'd have to defer to the coding expert.

Gil Astruc: Q2047 code and that's the only code that we have. I'm Gil Astruc for Takeda Pharmaceuticals. So it's the only coding that we have and then also for ICD9 coding where, we've only had two codes 285.21, that's for anemia and chronic kidney disease and end stage renal disease patients and then 585.6 for end stage renal disease, so those are the coding limitations that we have.

Carl Jeffery: And those are governed by the distributor?

Gil Astruc: It's governed in by the FDA,

Carl Jeffery: Through the FDA? But it's up to the payors then to set the coding to not accept any coding other than those.

Gil Astruc: Right.

Carl Jeffery: Okay so and right now…

Coleen Lawrence: Carl this is Coleen.

Carl Jeffery: Yeah.

Coleen Lawrence: Sorry, can you have the gentleman say the first code, what was he talking about?

Gil Astruc: The first code is our Q code, 2047.

Coleen Lawrence: So you are talking about the HCPC code?

Gil Astruc: No the HCPC code is a J code that will be coming in January. Initially we started out with a J code… A miscellaneous J code 3490, then we got the Q code and in January we should have the permanent J code, HCPC code.

James Marx: Okay I'm confused why we are even, why we are even concerned with this, I mean it seems to me that this is, this particular drug is locked in already and has very strict criteria that far exceed any prior authorization sort of limitation, so I, are we going over the entire ESA list with it and changing the whole criteria for all the ESAs or what are we doing?

Carl Jeffery: And this is Carl, just to clarify is just an addition for the Omontys, it's a new class into the ESA…

James Marx: Right.

Carl Jeffery: It's a new drug into the ESA class so since we already have criteria for the Epogen and Aranesp, we wanted to include this as well, but have the Board keep in mind too that because this is only a physician administer drug, it will only be billed through the coding from the PAD claims.

Dave England: So then this is Dave England, I have a question, if I understood the representative correctly, this is only available and only distributed to dialysis centers?

Brian Gwyn: Yeah that's correct, this is Brian Gwyn.

Dave England: If there was a patient on home hemodialysis dialysis but isn't going into a dialysis center and this is, asgood a product as you are claiming, they wouldn't even have access to it, they soon might have access to the other two, right?

Brian Gwyn: Typically a home hemodialysis patient still has visits usually once per month whether those are peritoneal dialysis or home hemodialysis for medication and check-ins so they would be able to get the medication in the dialysis facility.

Dave England: Okay then that would have to have been in the facility, it wouldn't be at home.

Brian Gwyn: Theoretically if the patients have been trusted in the past to give their Epogen at home, they could be given the Omontys as well but it would still have to routed through the dialysis facility and be distributed from that facility directly to the patient, if they weren't due to take it home.

Paul Oesterman: It sounds to me like you are then authorizing a dialysis center to act as pharmacy and dispense the medication for administration at home.

Brian Gwyn: It is, this has been the practice for Epogen for you know the last 20 years, if there are patients that can demonstrate that they have compliance with it, and they are able to self-administer at home, their ESA, they have been doing so for the past 20 years with that one to three week kind of regimen, with this once a month regimen, you could either have the patient administer at home or you could set the bar to say, you are only going to get it when you come into the facility, I have seen physicians throughout my territory do both.

Paul Oesterman: But then Epogen is available from pharmacies? This product is not available from pharmacies and I think there is a discrepancy there.

Brian Gwyn: Correct.

Coleen Lawrence: And I guess they should be announcing you know. So Carl, Carl hasn't made his presentation yet?

Paul Oesterman: Not yet.

Coleen Lawrence: Okay. Al right, I'll let Carl do his presentation.

Paul Oesterman: Okay, one of the real quick questions that I have is… It seems like in September we've had 33 claims. That's a fairly significant number for a product that is somewhat restricted so, I'd be curious to know if that's coming from a single dialysis center or if it's something that they're all jumping on this you know band wagon of the new product?

Chris Shea: As compared to Epogen I'd like to know what the Epogen number is because I think that's probably going to be quite high compared to 33.

Paul Oesterman: Okay, thank you for your public comment, Carl would you like to go ahead proceed with your presentation and I ask that our guest speaker not range too far away, because I'm afraid they'll ask him additional questions.

ii) Discussion by Board on Review of Utilization Data

Carl Jeffery: Okay, this is Carl Jeffery again for the record. I don't have too much more to add, I think Brian did a good job of covering the clinical studies that I was going to go over and I mean that you can see that the utilization is really spiked here in September. If I can narrow that down to providers but again I just wanted to stress this is only indicated for the dialysis, patients on dialysis. My concern is that they mentioned that they've got coding in place and I don't know if this is the avenue it but it sounds like as Medicaid goes, we need some coding in place to assure that we're only paying for those indications and from those providers potentially and… So I'm not sure what kind of coding we need to in place to make sure that we don't see inappropriate use for this.

Chris Shea: Well if the coding is not correct it's not going to be approved right? I mean.

Carl Jeffery: Well but we need to set that in our system to look for those codes, so right now we don't have any limits on this. So potentially if an oncology center got ahold of this they could bill it, it would go right through and so I know you've got your safeguards in place and I'll just…I guess I could wait to ask my questions but you know my first question was is that company seeking more indications for this that we'll see down the road?

Brian Gwyn: At the current time we're not seeking any additional indications.

Carl Jeffery: Okay.

James Marx: This Jim Marx again, there is a disconnect here because I don't see how a prior authorization would ever take place because the people who administer it don't even routinely request prior authorizations and we're creating the criteria that no one would even ever access. We have claims but there is never been any process to do prior authorization on this particular item anyway. So I think we've got a solution in search of a problem here I just don't see where we are going with this?

Coleen Lawrence: So Dr. Marx, this is Coleen. So we have ESRD facilities which we call the provider type 45s in our system and they could be the routine users of this drug and they can't seek prior authorizations within our system. And so some history and background right now, Medicare has just recently, I don't know the time range within last year. They are rolling over their payment methodologies and right now this class of drugs are beginning to change their payment methodology with Medicare. We have not at Medicaid, the majority of our patients at the ESRDs are on Medicare but there are a large portion for us that are still outside the Medicare schedule. We will be changing, and we have some web announcements out there right now that we've been communicating with providers that we are going to be eventually following Medicare where these drugs will be coming into the payment schedule of the facilities but we're not there yet. Okay so as far as there has been some kind of talk about the cost and that type of stuff of the drug, it will be rolling into the perspective payment schedule but we're not there yet. So clinically we do have criteria already set up for these drugs. I think the goal right now is that this drug is not included in our policy it names a handful of drugs, I think we say Procrit Epogen and we do not name this drug right now. So the goal is to include this drug into the same criteria. And we do prior authorize these drugs right now.

James Marx: Okay, thank you I stand corrected.

Chris Shea: So I'm a little confused because when I spoke to the state of Omontys I was told the Omontys did not have a prior authorization currently and that's why we are doing this review.

Carl Jeffery: Correct, that's correct.

Brian Gwyn: That's correct, I just wanted to clarify.

Carl Jeffery: Currently we do not have prior authorization or anything.

Coleen Lawrence: That is correct, that is why we are here today because Omontys was not in the prior authorization schedule.

Chris Shea: Right okay, I thought you said something else, okay.

Dave England: This is Dave England, just this other question I have is I know, you reviewed a lot of medications on the market right now that have limited distribution because of specific, unique monitoring requirements or criteria that needs to met for patient safety like

when Clozaril first came out and we had to be sure we're monitoring the patients outcome closely. I'm just kind of curious as to why this particular product that's marketed to compete against Epogen, Aranesp or the other ESAs had such a limited access to the public out there and can't go through pharmacies. It can only go through dialysis centers and is there something unique about its monitoring or the way it works that it requires this specificity or uniqueness of availability?

Brian Gwyn: This is just an agreement on the part of Arthimax and Takeda Pharmaceuticals with the FDA when we sought approval for the drug. We would if approved in dialysis centers only and distributed to those centers.

Dave England: Thank you.

Paul Oesterman: This is Paul I just have a question probably for Carl in terms of the clarification. I'm looking at the September claims and there are total of 33 claims and this is a product that dispensed once a month. Why are the quantities dispensed 80? Looking at package size and I look at prior months, there is not enough information here to be able to tell.

Carl Jeffery: I would say the package sizes are anywhere from point five to one ml and I… Yeah I don't have an answer.

Paul Oesterman: Okay.

Coleen Lawrence: We can get you though backup data on that, the claim history though.

Paul Oesterman: Okay that'd be interesting to look at for next time if we can get that please.

Dave England: There's 80 more for 30 days.

Paul Oesterman: Right.

Coleen Lawrence: There is more, it's okay if based upon what you are seeing on the… I guess the delivery model access you know do you want the criteria to be different? I'm asking you because I don't know; I mean is there a difference?

Dave England: I'm just thinking out loud here the fact that if it's made, if it does the same thing that other ESAs in the market do and it's new to the market and it's a beneficial for all patients, whether they're on dialysis like all others are on dialysis. I'm kind of curious as to why something had to be negotiated or established within the even FDA before they released it into the market as to why and become at a point had to be it so narrowly available to the public. It just seems this…

Brian Gwyn: Okay I can answer that.

Dave England: I'm comprehending why we have to have a narrow scope of availability.

Brian Gwyn: So if you look at the history of ESAs use over the last ten years, there has been a lot of restriction and controversy about ESA use in nondialysis patients. So in dialysis it's clear that patients that have an anemia to be treated for anemia and CKD outside of anemia I think it's less clear. There is a few different trials that came out which I briefly spoke about in the CHOIR, CREATE, and TREAT which actually saw an increased risk in cardiovascular events in the CKD patient population and so I think the FDA is specifically sensitive to these drugs and that patient population and with our product since we only apply for the dialysis indication, they wanted to make sure that it was only used in that patient population.

Dave England: If that is the case then in about a year to two are we going to be seeing you back here again saying you have an enhanced indication for patients. You know the same sort of indication they offer the other ESAs and then we're going to be going through the same routine. But then it will still only be available through dialysis centers and now they won't be available through oncology centers.

Brian Gwyn: Yeah but there is no trials that have been started or planning to begin in any other indication besides dialysis and of course those will take years to finish.

Dave England: Okay now I know I wasn't planning on making any amendments that this be available, can't argue with the Feds, right? And so I was kind of curious why we go this limited availability?

Coleen Lawrence: Well I mean just because I know the Board's decision's always been to align with safety and those types of things and with the public comment also would one want to amend the patient receiving dialysis? Do we need to modify what type of dialysis or where the dialysis is being received?

Paul Oesterman: I think we also need to amend the addition of the word "adult" in there. Let's see then, do we want the patients receiving dialysis at a dialysis center versus home dialysis? Dave I'm kind of deferring to you…

Dave England: Yeah I'm coming, I'm thinking, I'm thinking here. I hadn't gotten down to that level of detail, just thinking in broad terms. So again not off the top of my head has there been an issue with this in this dialysis center. So this is being used on children. Is this limited and is an age limit on the children being used and does this specifically have to be administered in the dialysis center? Or it just has to come from the dialysis center.

Brian Gwyn: Yeah so this drug is only indicated for patients over the age of 18 and there is no restriction on where the drug is given and so it is not contraindicated for home hemodialysis it is not contraindicated for peritoneal dialysis and the route or where they get the medicine is up to the provider and the physician. So it could be at home but it would have to again be given from the dialysis center.

Carl Jeffery: And Dave this is Carl. Real quick to clarify, this drug has not been evaluated in patient's less than 18, neither has Aranesp or Epogen. I think it's hard for parents to volunteer their kids for medical studies.

Dave England: Alright let's see, I don't see where it specifically says it on here. I know, because on here it doesn't really indicate this is like for adults 18 years of age and older…

Carl Jeffery: Well you know kind of add caution in there it is limited to 18 because you're drawing lines in the sand like that and even though it's not shown we don't have those kinds of restrictions on the Aranesp or Epogen either so I kind of hate to tie the hands of their prescribers and the clinical call centers to say stick with that age 18 limit. Maybe they've got a fifteen year old that's adult size and could be dosed appropriately even though I know our friends across the table here won't nod their heads and they won't to say it's okay but I certainly don't want to tie the hands of their prescribers and the…

Paul Oesterman: Well I don't want to put us at risk with approving something in a patient under the age of 18 if it's not in the approved criteria for that medication.

Dave England: I mean that's a good question because I know when I was doing some clinical practice, one of the controversies we had at one time was that having premature children there wasn't literature support out there to use ESAs at the time because they'd just barely came out. So the question is, do you give premature infants or neonates ESAs if they have anemia issues or kidney dysfunction issues or not. And so again that's why it would be difficult to say we should limit this to 18 years of age or older because I know a lot of medications can be used for off label uses if you have basic literature support to justify it. Do our call centers inquire or go into this level of detail? We have a practitioner calling in and saying I need to use this for this specific patient for not a FDA indicated use. We do have literature support if we could get literature support could we say we could do this with that, does that come into peer review in that event?

Carl Jeffery: Yeah we've given the call center liberty to use their clinical judgment so if despite if our criteria says 18 and the provider calls up and says he's got some peer review or some experience to say that yeah we've used it in kids less than 18 and it's safe and effective then the clinical call center has that ability to approve that.

Dave England: Okay I don't know I can see where you come from but I can't get my head around the verbiage we don't want to use that.

Paul Oesterman: Even if the FDA indication is for over the age of 18 or 18 and older and the company wants to allow and research to be done to demonstrate that the product can be used without adverse effects in patients under the age of 18 then that is actually technically investigational use and a company should be providing the product if they so choose at no charge to the patient.

Dave England: With that understanding, I would amend our criteria then is limited to patients of 18 years of age or older as per current criteria.

Paul Oesterman: Okay so at this point we don't have a motion yet or a second obviously if we don't have the motion for the proposed prior authorization criteria for Omontys, so we will need that before we start to amend this criteria. For my clarification failure to approve any prior authorization criteria would allow it for open access is that correct?

Coleen Lawrence: That's correct.

Paul Oesterman: Okay.

Dave England: With that understanding we accept our criteria as proposed by our consults?

Paul Oesterman: Does that include the over the age of 18 or older?

Dave England: Yes with or without.

Paul Oesterman: Section five, the patients must be aged 18 or older and so we have a motion do we have a second?

Chris Shea: I'll second.

iii) **For Possible Action**: Adoption of Clinical Prior Authorization Criteria

Paul Oesterman: So we have a motion and a second for the proposed prior authorization criteria to now include the Omontys product and to be used for anemia secondary to chronic kidney disease a patient must meet all of the five criteria beyond dialysis other causes have been evaluated and hemoglobin levels and the patient's age and the prior authorization will be for one month. Any further discussion?

Chris Shea: We're just putting on the amendment this is an amendment not the underlying motion?

Dave England: Well the motion was made to accept this with that change to add a number five the one under number one A, then go down, I double I and three and that would be 18 years of age, 18 years of age or older applies to all the patient populations

James Marx: I have a question under the posting of this, the only action item is presentational, using clinical information. We're going over all the other ESAs and I don't think that's posted and I don't think we've explained properly posted so we're actually acting on other drugs that aren't close to them, in the public listing.

Darrell: I see what you mean. But we're going to talk even when we're comparing with all the other ESAs.

James Marx: Exactly.

Coleen Lawrence: Dr. Marx, this is Coleen, I don't think you are amending any of the other ESA criteria. This is where you see what the other ESA criteria is and you just made an action on Omontys, right?

James Marx: You know I thought we were adding…

Paul Oesterman: We were adding the age limitation to this.

Carl Jeffery: If that's, so we have public comment and then if we are adding the age criteria to all of them.

Vinson Lee: Hi, this is Vinson Lee again, pharmacist with Amgen medical liaison, if you are going to add it to all of them, if you look at the prescribing information for both Epogen and Aranesp, we do have data to support utilization in children under the age of 18 so I would have an issue with adding that to the other ESAs as well.

Paul Oesterman: Great, thank you we are hijacking the same discussion here right now, because of the way this was presented with the agenda, if we were to change the age criteria or any criteria for theseproducts it would have to have been previously acknowledged so we, at this meeting today we cannot put the age criteria on any of the other ESAs but we can come… You know look at the age criteria as if it is, relates to Omontys.

Dave England: And then with that in mind, I will resend that motion but the motion will be solely to accept as is with the change of adding that under the Omontys section B, A, 1 AB would be the 18 years of age rule then.

Paul Oesterman: Okay, so that was the amendment, Chris you had seconded.

Chris Shea: Yeah.

Paul Oesterman: Okay, so we have the motion and second for just as presented with the Omontys, a prior authorization criteria with the addition of 1A5, the patient must be 18 or older, any further discussion by the board? Seeing none we call the question, all in favor please indicate so by saying aye.

Speakers: Aye.

Paul Oesterman: All opposed say nay, motion carries, and thank you.

Coleen Lawrence: Mr. Chairman can I just do a bit of a reminder. There are a couple of comments about coding, since you guys are out there manufacturers, doing sales on these drugs, please note that we require billing of these drugs with NDCs so Q codes, J codes, all those codes do not work for us, so when you are selling these drugs or promoting these drugs out there, we require the NDC for a physician administered drugs, okay.

e) Presentation of Short Acting Opioids use and clinical information
i) Public Comment

Paul Oesterman: Okay, moving on with the agenda, our next agenda item is the presentation of shorting acting opioids, do we have any public comment on this topic? There is none up here in Carson City. It doesn't look like there is any in southern Nevada or Las Vegas so Carl go ahead and present what you have.

ii) Discussion by Board on Review of Utilization Data

Carl Jeffery: Sure, I'll keep it short because there is really nothing new with the short acting opioids and the reason I bring this up is, was prompted by the, I was talking with an inspector over in California who mentioned that Oxycontin has been reformulated to limit the abuse of the Oxycontin. People are often seeking the Oxycodone 30 milligram tablets instead of the Oxycontin, it's an immediate release tablet they can easily be crushed, you know I think it dissolves easily and in liquid so that you can solubilize it and either inject it or smoke it somehow. So it's why we were kind of looking at this, and if you look at the utilization and see that we've had, just in the past six months, almost a million quantity, a million tablets of the Oxycodone 30 milligrams dispensed, so it's quite a few, you look at just the Oxycodone use alone and it hovers right around 13 to 1400 claims every month and even though this is a generic product we are still spending a pretty good chunk of change on these medications as well. So like I said I'm not going to go through all the pharmacology of the long and the short acting opioids, I think we now, have a general idea but I think what we wanted to get to here was to really limit the quantities that we've got listed here on our PA form. Then to exceed and maybe we need some clarifications here because, , this criteria is really to exceed those quantities and so I believe we've got pretty generous quantity limits on those short acting opioids and so anything that would require that above those doses would need some kind of clinical, you know they'd have to meet that criteria here.

Paul Oesterman: Carl this is Paul, just a point of clarification where we are looking at quantity limitations, we are not looking at sort of say total milligram limitations. So in theory a patient on a hydromorphone could get 180 or less, two milligram tablets every 30 days and as well as four milligram tablets every 30 days, without having to go through the prior authorization criteria, is that correct?

Carl Jeffery: That's how they are written here, yes.

Paul Oesterman: Okay, thank you.

Dave England: Carl this is Dave England, another question here is that how does this increase use of this? How does this square with the narcotics task force? Have we seen a big increase in this on the streets too right now? Do we just jump up like that when there isn't anything coming from the narcotic taskforce?

Carl Jeffery: I haven't spoke directly with the Nevada taskforce but I, when I spoke to the California, they have seen a big jump up as well with the organization in California that does this because we…

James Marx: You know I think, this is Jim Marx that there is a couple of reasons why first of all that the Oxycontin is becoming, the numbers are going down, the oxycodone short acting,

they are going up. First of all, there is a lot of people who have lost insurance coverage, so a lot of patients have had Oxycontin coverage previously which can cost several thousand dollars a month are now in a situation where they may have been on, you know 160 or 300 milligrams a day of Oxycontin and now their payor is covering you know 2000, 2500 dollars in bills and now they arewithout insurance, and there's no way they are going to pay that, they basically get diverted to the short acting which, personally I don't have a problem with that. I have actually done that with a lot of patients, my only concern is having a quantity limitation. One of the other big issues I think with the opiate prescribing is that patients were started on too high a dose and because of that they developed tolerance very rapidly and we've sort of move them up from their training wheels to, you know, to the big wheels and I think we should do whatever we can in our power to encourage the use of the tens and the fifteens, even the fives when they are available. So to me putting a quantity limitation on that actually prevents that/All of those lower dose forms also actually have much less street value as well so I think that it will be a sort of an educational move on the part to divert some of that, no pun, on the use of the word but divert some of those higher dosage prescription forms to lower dose and more quantity and unfortunately that's what's happening.

The problem that we are seeing now is that because of the independent distributors, the cost of Roxycodone and Oxycodone has gone up tremendously in the last year and a half or so and what, as the unattended consequence of that is now we are seeing a lot more heroine use. Because heroine is readily available, it's very inexpensive and you've actually diverted a lot of the diverted legitimate traffic to the illegitimate, you know illicit drug scene. So this is a very complicated, very complex issue and I have concerns with that first of all, second of all I have a real problem with meperidine, certainly 240 units, you know that meperidine is one oral form that I have never used in 30 years. I think it's poorly absorbed and if it is well absorbed there is the high risk of complication probably far more than any of the other opiates and far more in the way of interactions as well. Hydromorphone is much more desirable on the street, I would like to see some of that hydromorphone use diverted to some of the other…either the oxy's or even more plain morphine. So that's just a couple of my comments.

Coleen Lawrence: Dr. Marx some things that may be looking at the duration of the use of the prescription or also the type of the prescribers that are using the prescription or the amount of the prescribers that the recipient is utilizing.

James Marx: Well I think from the task force, indications are that it seems that a lot of the high dose, a lot of the high unit dosing is not coming from what you might think would be appropriate sort of sources and that really is an issue. You know a lot of the very high per dose or high unit prescribers are not what you would traditionally associate with particularly high requirement patients. So that's a problem and it's more of law enforcement problem and an enforcement problem and frankly that isn't being addressed at all because there is just a lack of resources in the state to address those issues. So I think all we can do is try and channel usage to lower dose forms and not be quite so sensitive to the number.

Coleen Lawrence: I understand, I mean we obviously work with the task force closely behind the scene on our reports, that's how we do our lock in program. I'm saying iwhat if we put in some things other than our quantity limitations, B such as the duration of therapy. We could

do things creative, as to say that, after a while, you know, duration therapy needs to cease or the number of prescribers that we see. We can do things like other states are doing, starting to view profiles with recipients and providers, those type of things, that [their boards] they are working on.

James Marx: Right and Medicaid has a direct access to the task force already, so I don't think that is really too much of an issue. I am not quite sure how to address the whole issue. I think that we don't put a duration and limit on people getting hypertension treatment or diabetes treatment. I think the issue is what is the underlying diagnosis to cause the prescription in the first place and if it's an acute injury or a fracture or something like that [post-operative], that's one issue. If it is chronic pain that's an entirely different diagnosis and you know, generally chronic pain by definition is chronic and it's not going to go away in three months or six months.

Dave England: What if there were the option to require some sort of escalation, it has to initiate with the strength. And go to the strength in a specific time period, and I realize that that's maybe tying the hands of some of the prescribers because again the problem we're having with this is we're walking on that fine line between where is the art of medicine, what is the legal practice of medicine, what authority do we as regulatory boards have to come into that, that equation, and where because again this is ridiculous. I didn't think that you made that stuff anymore, I was surprised that meperidine is still on the market but at the same time, it is kind of scary because of the insurance situation and the economic situation, that we are basically pushing our population into using other things that in essence, and if they already got that big of a buy in, they could start selling on the streets and probably be better off than when they were working, which is an even worse situation.

Carl Jeffery: With permission of the chair, looking back at our experience just now with Forteo and Prolia the next item on here is long acting opioids, perhaps the board would be best to look at this because they are connected. And so maybe it would benefit the board to look at this in a bigger picture, let's look at the long acting opioids at the same time as we are looking at the short acting?

Paul Oesterman: This is chair Paul and I concur with that so let's try to consolidate these two and look at them concurrently.

James Marx: I think that's a great idea actually and I think that what we want to do is I think we want to move the chronic pain patients into the long acting forms but on the other hand I think that we really, I realize that we are a regulatory board of some sense but I think that even regulatory boards can enforce some sort of good practice. I think that we have in fact done that in a lot of other cases and I think good practice is just to start with the lowest effective dose and by making the high dose form so readily available, it let's those that are maybe not so knowledgeable and sophisticated start prescribing these higher doses. Of course all patients want the higher dose forms because you know, they actually have much more street value and to give somebody a five milligram tablet they are not, they are going to tell you, oh I need to take a lot, well that's fine give them more of them, but they are going to have a lot less street value and that's going to be a lot less inclination to divert that medication. Plus I think that there are some patients that actually legitimally take it and we

are starting those patients on way too high a dose in the first place, and that is a big part of the problem we have with so many patients a 180 milligrams a day, when they probably could have been at 60 or 90 milligrams a day or maybe even less. So that, I think we've, by making the 30 milligram so readily available, we are actually encouraging their use.

Coleen Lawrence: So Mr. Chair let me give you guys a little tidbit, the last two weeks we have been in provider training and there are some statistics related to the providers. From January through October we spent, we are now a medium-sized program, so when you guys say you're a regulatory board, you are an advisory board for the Medicaid people. The people service, the overall program expenditures from January through October was 1.4 billion dollars that's how large our program is for Medicaid now.

Coleen Lawrence: 1.4 billion dollars is what we've spent in Nevada Medicaid, Nevada check-up, okay? We are now servicing 307,000 recipients for our program and there is 17,000 Medicaid providers enrolled into our program. On average now, we are spending about 34 million dollars a week in our program. So when you see these program numbers, it kind of puts it in perspective about what our population size is. Our prior authorization program and what you do is for the [people] service program, however the managed care program mirror a lot of things that we do on the pharmacy program and all our people service program.. So yes, we are an insurance program. Nevada state health insurance program for the Medicaid and the Nevada check up program. So it is a very large task that the DUR board does have, so yes we are a one point four billion dollar program now, and that was just up until October, we just did our largest cycle of expenditures that we've ever done last week. I won't give you the number because I don't remember from the top of my head because they told it to me after I gave that last tidbit last night. So those are some tiny numbers for you guys to kind of have and seehow big is our pharmacy program.

James Marx: This is a question I have for our physician members.Would we be out of line, would we be tying your colleagues or other colleagues hands by maybe implementing the APS American Pain Society guidelines for initiating and maintaining analgesia. If we implement those, as the standard rather than try to deal with it ourselves, you know we just implement that without really tying peoples' hands and make it difficult to practice.

[Indiscernible] Dr. Marx, I don't know about the Osteopathic Board but I know the medical board, I actually was at the legislative council hearing where those regulations were formulated and actually adopted by reference the federation of state medical licensing boards which actually uses the APS , American academy of pain medicine and American society of addiction medicine criteria, so that's actually part of the Medical Practice Act already.

Dave England: The other question I have is how many of these patients on these medications on this list have we had on lock in or lock out? I mean we're trying to see that kind of usage I'm wondering if we're going to see the same thing, same trend with that that we did with our Marinol folks. You know, if we have possibly this kind of abuse going on, are we putting them in the lock in program?

Carl Jeffery: Well you know Dave, this is Carl, every month we are probably adding 20 or 30 recipients to the lock in program We still, when we run the query of our criteria, 10 or more controlled substances in 60 days with two or more pharmacies and two or more prescribers and we still get a list of more than 250 recipients every month. So it's a, it's still a pretty lengthy list and we are tackling it little by little but it's hard to just put a blanket lock in, on every one of these recipients.

Coleen Lawrence: The lock in criteria for long vs short acting opiates are completely different.

James Marx: Because I mean, just from my… you know just a quick overview it seems like if the American Pain Society and the Addiction Society guidelines are all in place, and we're still having this kind of use, if we're going to be maxing out our Lock In ability to do that, what more do we have that we could do to get a handle on it?

Coleen Lawrence: Other states are doing things like audits they're doing profiles, they're doing things like more education. We do have… we do not have honestly, the most aggressive quantity limitations that we've seen through other states' practices. Some states have a complete quantity limitation cut off and require a prior authorization after quantity limitation. You know, you're done after that month and that's it for the month, those types of things. We do allow for a prior authorization after that month. Things like what your diagnosis is dependent upon where the cut off comes into play for those type of things.

James Marx: You said our prior authorization is in effect for six months, should we drop that down to three months? I mean you know I'm trying to think how we can do this practically because it's going to be, you know, there might be some… it might seem good, what we're doing right now, but I can just see what's going to happen in the pharmacies, and the physicians' offices. I mean six months from now it is probably an issue, three months what would that do? But then what impact is that going to have on practices out there?

Coleen Lawrence: If you're more comfortable we could also come back with a menu of options for you from what we've seen in other states. If that is… is more entertaining to the board, if you would like that.

James Marx: I think that might be a good idea to look and see what's being done in other states and then try to consolidate both the short acting and long acting together into a single recommendation.

Indiscernable: Dr. Marx I certainly concur with that, I wouldn't be too hung up on what other states are doing, I think there's a lot of misinformation and a lot of draconian type of measures that are being taken that I don't necessarily want to subscribe to. Dr. Marx: For example, Washington State wants the limit to 100 milligrams of morphine equivalents a day which is you know, not really very much medication in the scheme of chronic pain treatment. I think in the terms of prior authorizations to make them more frequent. What's going to happen is that less and less doctors are going to prescribe these opiates which are appropriate treatment for a substantial number of patients but are also obviously not substantial for a number of people that are probably diverting, improperly using the medication. I can tell you

just from my very small practice. I only see patients two days a week and we spend an additional two days a week doing prior authorizations after seeing patients two days. So it is a… it isn't that inconsequential degree of overhead that you're imposing, I think perhaps one thing that could be done is that just like when you certify patients for handicap placards and license plates, they'll be some sort of time limitation on the prioritization. So for example if you… you may certify someone for life, I mean for example, versus someone else that may have an acute type problem for one or two or three months. So that way it sort of puts some sort of limitation on the utilization and requires some sort of re-evaluation.

I think that most legitimate prescribers wouldn't have a problem with that and I don't think most of them would certify patients for substantially longer than would be appropriate. I think the problem is once you get this prioritizations going, they tend to be sort of self-perpetuating and that's probably not a good thing either. So I think by putting the limitation on the length of the prior auth I think that might be a way of addressing this and maybe reducing some of the burden on the more chronic patients and perhaps putting a lid on some of the patients that are maybe more acute who probably should be cut off at some point.

Paul Oesterman: Okay, I think that's a very viable approach, and my recommendation at this point was that we consider a motion to table the discussion until the next meeting on both the short term and long term opiates and then we can take a look at the information from the other states that you can provide to us, so I'm going to ask for a motion to table the discussion.

iii) **For Possible Action**: Adoption of Clinical Prior Authorization Criteria and/or quantity limits

James Marx: I'll move that we table both these issues until further information is available.

Paul Oesterman: On this motion, can I have a second on that motion?

Chris Shea: Second

Paul: Okay so we have the motion by Dr. Marx and seconded by Chris, any further discussion at this point, I think we had some very good discussion and we are going to be able to move forward with more information at the next meetin. So let's call the question; all in favor of tabling the discussion indicate so by saying aye…

All speakers: Aye

Paul Oesterman: All opposed say nay…

f) Presentation of Long Acting Opioids use and clinical information
i) Public Comment

See Above. Tabled until next meeting.

ii) Discussion by Board on Review of Utilization Data

iii) **For Possible Action**: Update of Clinical Prior Authorization Criteria and/or quantity limits.

See Above. Tabled until next meeting.

g) Presentation of Cymbalta use and clinical information

i) Public Comment

ii) Discussion by Board on Review of Utilization Data

iii) For Possible Action: Update of Clinical Prior Authorization Criteria

Paul Oesterman: Very good okay our next topic on the agenda was the discussion on the presentation of Cymbalta and at the beginning of the meeting that was deferred to the next meeting. So the next item that we have is item number five which is the DUR board requested reports and the first report on that was our utilization of the Promethazine with codeine during quarter two and quarter three of 2012. Carl why don't you go ahead and describe this report.

5) DUR Board Requested Reports

a) Report on Promethazine with Codeine syrup use

i) Public comment

ii) Discussion by Board on Review of Utilization Data

Carl Jeffery: Okay just similar to what we saw last quarter and just kind of holding steady, it drops down in July and August and kind of seems to correlate a little bit with cold season but still about 500 claims a month that we're seeing here, still a good… not a ton of money. I guess for about almost 5,000 dollars used on those. So this was just a request to present this to the board. I'm open to continuing to produce this one or if you want me to come with some recommendations for maybe some prior authorizations or quantity limits for these agents.

Indiscernible: What's the quantities dispensed Carl, is that ounces or is that…?

Carl Jeffery: That'd be milliliters.

Male Speaker: Milliliters, okay.

Paul Oesterman: Do you have anything left there for public comment in your audience?

Carl Jeffery: I don't. We've got a few members of public hanging out just to watch us and…

James Marx: Okay and make sure you behave. Okay so I just want to make sure that if anybody has any public comment on promethazine with codeine use that they do have the opportunity to speak before us. One of my concerns on this is having a future report to be

able to take a look at because it doesn't seem like the usage is you know somewhat consistent over the course of the year. But how many patients are using this for extended periods of time, you know I can see short term use for cough or cold regardless of the time of year, but if there are patients that are taking it chronically year round, that might be a thing to look at and that might be the case when we would want to consider some kind of prior authorization for extended use.

Carl Jeffery: That's certainly an option, something we can bring forward next quarter is maybe we can put a limit on so they can get so many milliliters per year or per quarter or something per period So that's certainly something we can look at with this product too because you know even if they're not using it illicitly, maybe they're using it for side effects for their ace inhibitor or something so you never know what exactly they may be using it for but we can look at how many people are on it for extended periods of time.

Paul Oesterman: Just out of curiosity, I know we've been looking at this for about a year, did we… were we able to do any correlation with patients that are on this on a chronic basis, are they on ace inhibitors, are they on any medications that affect the bladder control and action because cough is a side effect of a lot of those medication, also do we have any correlation that this use coincides with any of those other concurrent utilized medications?

Carl Jeffery: I didn't pull any of those numbers but I think those are certainly good points and something we can… we can try to look at that as well.

Chris Shea: This is Chris, you know something that we used to get on DUR board was you know, there would be a topic similar to this, you know that would have data like Paul had suggested. You know do we have folks on promethazine with codeine for greater than ten days or thirty days or whatever that criteria happened to be and then the other provider would provide us with the different categories like that. You know how many folks did we have that were taking more than four grams of Tylenol in a thirty day period or on a high average. Are you going to provide us some of those reports too, can we ask for those types of things?

Carl Jeffery: Yeah certainly, you can always ask for those reports and I'm happy to put together whatever I can. So yeah, anything, something like that is certainly possible.

Coleen Lawrence: I think what Chris is looking for are the physician profile letters or retro DUR.

Carl Jeffery: Okay and we'll have those next meeting.

James Marx: Carl, one of the things I'm curious is if we could get a profile, other, if there's any other therapeutic classes that seem to be prescribed in addition to the Promethazine-codeine. I mean I'm always amazed when patients are on like hundreds of milligrams of morphine equivalence and need something for cough. I can't imagine that their cough reflexes isn't well suppressed from their underlying opiate therapy but they still want codeine for cough syrup. So I have a hard time dealing with that but I'm just curious. I suspect you might just find three people on ace inhibitors among these you know, hundreds of claims a month. So I don't think that's because of the widespread use of ace inhibitors that these

people are taking you know, romethazine and codeine.I suspect that if you look, you'll see a lot more on benzos. and things like that, that are not really associated with coughing. So I think that would be very interesting to look and see if there is some sort of symptom complex that seems to be characteristic,that seems to be common to promethazine and codeine patients, particularly the ones that are doing it chronically, month to month. I know there's some tremendous amount of abuse in this area even though it's, I'm very inexpensive drug it really, it's really abuseable and that's my concern.

Coleen Lawrence: Dr. Marx, we were just talking up here, just kind of brain storming, it's almost like when you profile some of these patients, we keep talking about controlled substances and everything almost hit and miss. It's like we're looking at we'll say long acting and then we'll say short acting and then we issue this report, but we almost need to pick a drug, and then profile a patient holistically, on a comprehensive view to say what is going on and find a way to report, trying to list out all the drugs that we can look at –and try to target some populations and report back to you.

James Marx: This is well, I think we have a suspicion of what is going on, but we need the data to document and then determine how to move forward. I think that's, you know, part of the responsibility of the DUR board to you know, make sure that these medications are available to those patients who legitimately need them, and they are prescribed in the proper dose, quantity and so on, but not used in excess or distributed to third markets.

Paul Oesterman: I totally agree, and I agree totally with Coleen too that we need to look at these numbers in holistic fashion rather than in a tunnel vision sort of way. I think we need to look at see what the full breath of these individual patients are, which obviously it becomes a more complex analysis, but I think that we really need to look at this holistically to really get a better handle of what the actual utilization is and who's utilizing these drugs may be in an inappropriate way.

Paul Oesterman: I think we've had some really good discussion and what I'm going to propose is that I speak with Carl and Coleen offline and we determine what data we can assimilate and then present it at the next meeting.

Carl Jeffery: Yeah, sounds good. Thank you chairman.

iii) **For Possible Action by the Board**

b) Presentation of List of Outstanding DUR Board Report Requests

i) Discussion by Board on Review of Utilization Data

Paul Oesterman: Okay, the next item on the agenda is 5B, which is a presentation of a list of outstanding DUR board report requests. It's up to the board now, to take a look at what we have, I don't see it.

Carl Jeffery: Right I didn't have any outstanding reports that I had left in my, we inherited a list of reports leftover from the previous vendor, and so we've presented all of those to my knowledge. If there are other reports that you want to add to that list then we can certainly

put those together for you and maybe this is part of the discussion we will have you know, offline Mr. Chairman.
Paul Oesterman: Okay, that sounds good, so we are current with the reports that had been requested. I appreciate your efforts on this, because I know it's been a bit of a challenge with the transition, so thank you.

6) Standard DUR Reports

a) Review of Prescribing/Program Trends
i) Public Comment
ii) Program Trends

Paul Oesterman: Moving forward to item number six which are our standard DUR reports. First what we have here is section A, the review of prescribing and program trends. Do we have any comments from the public on any of these reports? Seeing none, Carl would you like to go ahead and give us a brief overview?

Carl Jeffery: Sure this is a, similar to reports we've looked at. The first one on here is page 314 on mine; I think it's your first one after the tab there. You're looking at, with top ten therapeutic classes ranked by payment amount so this is quarter one, we have the quarter one listed by payment amount and claim count. So you could still see antipsychotics are still definitely high up there for the payment type. I think we're getting a little bit better with this as some of the more generics antipsychotics come out. It's certainly come down from the previous quarter. Although it was up from quarter four but the quarter a year ago is down significantly. Still the analgesics are pretty high up. If we look at the number of claims, that's really where the analgesics pop out with a lot of, still a lot of claims for the analgesics.

James Marx: And I think just as a reminder for the DUR board, while the cost is important, our primary focus is, should be on therapeutic outcomes and medication safety.

Coleen Lawrence: One thing I want to point out to the Board, for you guys is we were kind of looking at our pharmacy program because our costs jumped substantially for us, from the end of the last calendar year to this first calendar year, and we were just going over it and for me, being in this program for almost 12 years, I'm like, I've been feeling like something had to change. For us it's kind of good to look at that number first and we did from December to January, we kind of had a jump in a couple patients, and so as you can see the MOE class, we've had a couple of changes, if you look at therapeutic range by payment amounts, you can see first quarter versus second quarter went from RX count 48 to 55. We have had a couple of changes in you know.From January, we hit the two million dollar mark and it killed our budget there for a little bit in pharmacy. So we're just kind of watching that path a little bit we're watching what's happening in that area. Nothing substantial is changing it's just that we're just watching our numbers and the growth of our patients. We're having a growth in patients right now, for some reason, it could just be change in the economy, our recipient count is definitely changing both in numbers on Medicaid, so I can remember being on this program ten years ago, and that number now it's 45 and 50s, that number was like six, you know, 10 years ago. So it's definitely affecting our program.

James Marx: Just one question too. I know we talked about this before in the past but you know, we're looking at outcomes rather than cost impact. Do we have any way of showing the patients that end up on Medicaid. With the economy right now, it could be short termeso we may have some patients that are having acute health care issues that we can measure you know, is the patient getting better. But if the majority of our patients are chronic, have chronic health problems. So the issue is we're never going to 'cure' them so to speak but then we have data to show that we are able to keep…we've been able to keep hospital and ER visits down and that I can even show that the impact you know the things that we're trying to do actually have an impact.

Coleen Lawrence: Sure, absolutely. So you know I always see the services outside of the programs also so we can data mine. It's difficult to interpret but we can look at emergency room data or we can look at hospital data. I do caution you it's a little bit difficult in our systems just because we don't collect on DRGs. We're a pretty in-based, hospital based system on reimbursement but we can definitely try to figure out for you…

James Marx: I know it's always one of those things you always want to see outcomes but sometimes those outcomes are difficult to determine but it would be interesting to see if we already…have we been able to make any impacts of decreased ER visits and hospitalizations.

Coleen Lawrence: Absolutely you know the impact of you know asthma policies versus the ER admission rates those type of things. So yeah you know, if you come up with a question and you want to try and figure out what the answer is, then we'll go find the data.

James Marx: Especially with all the changes coming down the pike too with how Medicare seemed to be impacting payments on hospitals you know for HCO type groups and all their reimbursements based on outcomes now, it seems that the best way to look at the outcomes is are they visiting less are they using less medication.

Coleen Lawrence: Now remember Medicare Part D is covered under them.

Coleen Lawrence: So we're just getting the cross over claims. So the population that you have is fee for service. Maybe they're going to be in the managed care program unless you are in a rural area and then everybody is competing for the service program

James Marx: Okay. I'm just curious to see if there's any correlation with it,

Coleen Lawrence: Absolutely the pharmacy drives a lot of those outcomes so we can go look at whatever you'd like. So when you see a policy that you would have prior authorization on we can go look for the medical data.

James Marx: Thank you.

Dave England: I know for me one of the areas that always intrigues me is the anticonvulsants because I know that these medications crossover in terms of their indications. As we don't have this many patients with seizure disorders, what are they using them for and is it possible

for us to be able to maybe break down that category and kind of get a better feel for the indication because there we're seeing a lot of usage as well as a lot of expenditures.

Coleen Lawrence: Absolutely. Go ahead.

James Marx: You have to realize that the anticonvulsants are probably very seldom used by neurologist for treating seizure disorders, that they're used for bipolar disease, they're using for psychiatric medications, used for neuropathic pain. So there's a lot of…there are many more indications and many more actual patients using them for other indications that are…can traditionally associated with seizure disorder. So unfortunately that's probably a bad description of that drug class.

Dave England: Possibly we can get a report of those patients, the cross-overs. Their diagnosis with, you know any of these medications.

Coleen Lawrence: So we just ran a report, you know, we have the children who are on psychotropic medication. And in our policy right now we have anticonvulsants in there. And the Board made the decision that if you're on an anticonvulsant and you write an anticonvulsant diagnosis on the script, it bypasses my authorization policy, okay that's how it is currently written. So within this report that we were looking at the psychotropic policy, we just pulled out all those numbers that indicate a practitioner had wrote this anticonvulsants diagnosis on the script. We have those numbers already set aside for the psychotropic policy.

So we were going to present the report to you but I just haven't finished it…I wasn't quite ready so we'll go through it next time. hen we can also get that other bucket out there of anticonvulsants, now this is just for the children. That would give you kind of an ideaof the amount of anticonvulsants are out there for children, compared to the total population of anticonvulsants. o yes we can show you that piece of evidence and then we can determine regarding that total population of anticonvulsants also. o we do have some of that…those data already available.

Paul Oesterman: Okay great that should be useful information. Okay Carl back to you I'm sorry.

Carl Jeffery: It's alright. nd with those anticonvulsants it's kind of a challenge for us to collect that data because the pharmacies are…well like Coleen said, with the kids, it's a different story, but for adults the pharmacies are not required to transmit a diagnosis on their claims. So if they happened to transmit a diagnosis great we can capture that and we can report on that but with adults it's hard to capture that. But MMIS certainly does with the medical claims coming in, but again they're potentially putting several diagnosis on their claim forms on each claim so... But what we can do minor data with the anticonvulsants and the indications that they're using it for.

On the trends through the quarters we continue on with the antipsychotics definitely with a higher spend. When you get down to the top 50 drugs ranked by payment, I thought this was kind of curious too because like quetiapine jumped over the aripiprazole which was interesting because it's generic now. But we have several more claims, a lot more claims for

the quetiapine and the aripiprazole. ou'll see that as Coleen eluded to as well the antihemophilic product. We have a couple factor patients that are using 300,000 dollars a month on factor products. So as the Board, I'm not sure if there's anything you could do specifically for those patients, but I think that could be a potential area…see nine claims are 1.3 million dollars worth of payments.

Coleen Lawrence: And Carl I think there was some concern about the units and so we're going to start look atthe number of units and then also I guess we'll be doing is looking at clients with the drugs and things like that.

Carl Jeffery: Yeah. And the units are kind of funny because them…if…because they are…I've examined the units because the unit of measure is funny in those but you're right we'll continue to look at those. And I think that…I've looked at a few pharmacies there submitting those high dollar claims and it seems that they're submitting them correctly from what I can tell. As you can see Synagis has shown up for them and lives there for our first quarter…look for…I'm sure it's dropped off again because we're in a Synagis season for this last couple of quarters. And we still have the same Synagis criteria and reviews for a long time so unless somebody knows specifically that that…I don't know whether the criteria has changed we just looked at it again a little bit ago but certainly if the Board requests we can review the Synagis criteria but that's always a this type of therapythat gets pretty high use. But I think when you look at the overall spend its keeping kids out of the hospital so the cost benefits there.

We get down to the top ten proDUR edits from…starting with quarter one unless there's any other questions about some of the other quarters but I think they're all similar claims, similar numbers there. So look at the top ten proDUR edits, the TD over in the left column is a therapeutic duplication so, the top one that we're seeing is the hydrocodone and acetaminophen conflicting with hydrocodone and acetaminophen and that would be two different strengths. We get down at the very bottom there's two other codes, there's DD which is Drug Drug interaction and ID which is Ingredient Duplication. So when you see those two there…the ingredients the exact same drug that's being hit either with the same pharmacy or different pharmacy.

Dave England: Just one quick question and I'm just kind of curious if I may ask on the drug-drug interactions you know we often sit down with warfarin with all these medications. Even though it can interact with all of these, if it's been maintained and monitored, I mean have we actually had hospital admissions due to bleeding or to super therapeutic INRs or anything like that, prompting this or was it just a prompt that's coming across that says, we've got a drug to drug interaction but, it's a managed drug interaction.

Carl Jeffery: These would all be paid claims so the pharmacist saw this, it came up and they said, warfarin and simvastatin, they put the code in and it paid, so these don't correlate to anything we have in the hospital data, and we could try to pull that but I think that would be pretty difficult to evaluate those if we're looking for patients who have had a drug interaction and then later had an admission to the hospital.

Dave England: Because there are a lot of drug interactions that take place , in some cases you are given medications for that, drug drug interaction specifically, so I just want to make sure, you know, even though we're collecting the data, is it generally telling us something that is going to have an impact on patient care.

Coleen Lawrence: So these are interactions that have occurred at the point of sale and a pharmacist has said that they have given clarification code that says it's okay and has proceeded to fill the prescription, so if you want to go further and see… you know, I'm just going to make this up, you know, there were 16 hits on this drug-drug interaction, was there a subsequent emergency room visit within 30 days for that patient we could do that, not saying it was because of that, but a high coincidence.

Paul Oesterman: Kind along those lines and we got total numbers of hits, but I'd be interested to know, you know, how many of these interactions that showed up as a hit resulted in a change in therapy, you know, how often did either the call center or the pharmacist say, wait, we've got a, you know, a red flag here, contact the prescriber and then make a therapeutic interchange or something of that nature. Just seeing these raw numbers of how many hits there are, what are we doing about it, is what I want to know.

Carl Jeffery: Alright, that's a good question, I don't have that in front of me, we can see… so you want to know how many times they either hit and how many times they over ridden or how many they are actually not filled, so they get to this DUR and… okay.

Indiscernible: Yeah, it's because that, to me that shows that we're doing something, otherwise, all we're seeing is raw numbers here of… you know, okay, these interactions happened but it's sort of easy, to just hit the override button and so I'd like to be able to say, you know either pharmacist, and the physicians and practitioners are truly looking out for the care and results for our patients.

Dave England: Warfarin sodium and simvastatin we get 794 hits, but if you go down the row and we see simvastatin and warfarin sodium and we only see 536, shouldn't those be the same number?

Coleen Lawrence: Carl, this is Coleen I think we need clarification on this total when I think about it, are these just hits but we don't know if they actually filled it or it was just a hit, so I think when we look at our billing manual, they can go a couple of different ways, it could hit but it does not mean that they went further. . So I want to take this report and we'll look at how we modify it to say, what the outcome was on, whether it was modified after the prescriber was contacted?

Carl Jeffery: Right, I think that's a good point Coleen. And David, I think to answer your question, you know theoretically that those would be different between the simvastatin for the drug, drug interactions is because warfarin matters, it's so that the top ones or warfarin is in the left hand column, that's the drug that's being filled at that time and it's hitting the one in the right hand column and I think it's higher probably with this one because Warfarin is filled more frequently than simvastatin.

Dave England: Okay, alright, that makes sense, thank you. Okay, so from the Board it sounds like requesting a little bit further delineation of the RetroDUR report in terms of the impact and similarly the ProDUR.

Carl Jeffery: Yeah and speaking of RetroDUR, we're always looking for ideas, I just wanted to toss out to the Board if they have any specific topics for RetroDUR that you would like for us to address in the future?

Paul Oesterman: Well I think we've given you a couple of things already over the course of this meeting, but if the members of the Board have anything in particular at this point that they would like to have brought forward to the next meeting? Okay, Carl you've got enough to do, I'm sure next time our opiate discussion will be very productive and we'll be able to move forward on that so, are there any additional things that anybody would like to bring up at this point?

iii) Top 10 Therapeutic Classes for Q1 2012, Q2 2012 and Q3 2012 (by Payment and by Claims)
iv) Top 50 Drugs of Q1 2012, Q2 2012 and Q3 2012 (by Payment and by Claims)

b) Concurrent Drug Utilization Review (ProDUR)
i) Public Comment
ii) Review of Q1 2012, Q2 2012 and Q3 2012
iii) Review of Top Encounters by Problem Type

c) Retrospective Drug Utilization Review (RetroDUR)
i) Public Comment
ii) Review of Responses
iii) Status of Previous Quarter
iv) Status of Current Quarter
v) For Possible Action: Board Discussion and Approval of Future Criteria Selection

7) Closing Discussion

a) Public Comment

b) Date and Location of next meeting
i) Discussion of new time of next meeting.

Chris Shea: Hey Carl, this is Chris, I was just wondering if maybe for the next one you could bring what our current PA or if there's any PA criteria for a Singulair? We spent a lot of money on it, I'm not sure if it's even a prior authorization drug or not, is it a PA drug?

Carl Jeffery: It's a… no there's no clinical prior authorization for it, it's on the PDL and with the introduction of the generic recently, within the last 2 or 3 months, I remember when it came out there were multiple manufacturers, they were introduced at the same time.

Chris Shea: Is it a multi-source?

Carl Jeffery: Yeah, so it is…
It's pretty inexpensive anymore and we'll probably put our… if it's not done already then we'll have a MAC on it pretty soon.

Paul Oesterman: Okay then, is there any general comment from anybody in the public? Okay, with that being said, our next meeting is scheduled for… when?

Carl Jeffery: Let me look my calendar here to… I know we discussed this briefly a few months ago about moving into an evening meeting, but right now I've got January 24th as our next meeting.

Paul Oesterman: At this point we're still looking at different facilities to be able to accommodate the needs for both North and South, so at this point I say let's continue with scheduling and planning for January 24th at the same time, I know we can make firm arrangements.

Coleen Lawrence: And do you guys like the Thursday still Thursday was the best for you guys?

Indiscernible: Yes.

Coleen Lawrence: And when you talk about evening, when you talk about like five o'clock, not like late, we're just trying to figure out your schedules, if that works better, okay.

Chris Shea: Maybe we can consider meeting at Reno once in a while.

Paul Oesterman: Okay, so at this point our next meeting is tentatively scheduled for January 24th 2013, time to be determined, with that been said, I'd like to thank everybody for your participation today, I think we had a very good productive meeting and we will adjourn the meeting at about 3:30 pm, so thank you everyone, drive carefully.

c) Adjournment – 3:24 PM